UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

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| JAMES A. FOLEY,<br><br>Plaintiff,<br><br>v.<br><br>ELI LILLY & CO., and<br>Lily USA, LLC.,<br><br>Defendants. | : | COMPLAINT AND DEMAND FOR JURY TRIAL<br><br>Case No. 14-cv-4149 |

**COMPLAINT**

Plaintiff, James A. Foley ("Plaintiff"), residing in Fallingston, Bucks County within the state of Pennsylvania, by and through his undersigned counsel, hereby sues Defendants Eli Lilly & Company, and Lily USA, LLC ("Defendants") and alleges as follows:

**INTRODUCTION**

1. This case involves the prescription drug Axiron, which is manufactured, sold, distributed and promoted by Defendants, as a testosterone replacement therapy.

2. Defendants misrepresented that Axiron is a safe and effective treatment for hypogonadism or "low testosterone," when in fact the drug causes serious medical problems, including life threatening cardiac events, strokes, and thrombolytic events.

3. Defendants engaged in aggressive, print, television and direct mail advertising campaigns for Axiron.

4. As a result, diagnoses of low testosterone have increased exponentially. This has directly related to Axiron's sales increasing well over $100 million in 2013.

5. However, consumers of Axiron were misled as to the drug's safety and efficacy, and as a result have suffered injuries including life-threatening cardiac events, strokes, and thrombolytic events.

**PARTIES**

6. Plaintiff is a natural person and a citizen of the State of Pennsylvania and used the prescription Axiron as prescribed and directed by his physician.

7. Defendant Eli Lilly & Co., along with subsidiary Lilly USA, LLC, is a corporation organized and existing under the laws of Indiana with its principal place of business and headquarters at Lilly Corporate Center Indianapolis, Indiana 46285 USA. Eli Lilly & Co. has conducted business and derived substantial revenue from within this District as well as the State of Pennsylvania. Service may be accomplished on both Defendants' registered agent, National Registered Agents, Inc. 100 South Fifth Street, Suite 1075, Minneapolis, Minnesota 55402.

8. By way of background, Axiron (testosterone 2% solution) was submitted to the Division of Reproductive and Urological Products on August 11, 2006 by Acrux Pharma Ltd. Eli Lilly & Co., and Australian partner Acrux Pharma Ltd., received FDA approval on November 23, 2010. Upon FDA approval, Eli Lilly & Co. received exclusive worldwide rights to commercialize Axiron. Lilly USA, LLC operates as a subsidiary of Eli Lily & Co. Lily USA, LLC develops and run marketing campaigns for Eli Lily & Co., which includes Axiron.

9. At all times herein mentioned, Defendants, in interstate commerce and in this judicial district, advertised, promoted, supplied, and sold to distributors and retailers for resale to physicians, hospitals, medical practitioners, and the general public a certain pharmaceutical product, Axiron.

## JURISDICTION AND VENUE

10. This Court has jurisdiction over Defendants and this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiff and Defendants and because the amount in controversy between Plaintiff and Defendants exceeds $75,000, exclusive of interest and cost, and because, among other reasons, Defendants have significant contacts with this district by virtue of doing business within this judicial district.

11. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(a) by virtue of the fact that Defendants are doing business in this judicial district, subjecting Defendants to personal jurisdiction in this action and making it a "resident" of this judicial district.

## GENERAL ALLEGATIONS

12. This action is for damages brought on behalf of Plaintiff who was prescribed and supplied with, received and who has taken and applied the prescription drug Axiron, as tested, studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed, sold or otherwise placed in the stream of interstate commerce by Defendants. This action seeks, among other relief, general and special damages and equitable relief in order to enable Plaintiff to treat and monitor the dangerous, severe and life-threatening side effects caused by this drug.

13. Defendants' wrongful acts, omissions, and fraudulent misrepresentations caused Plaintiff's injuries and damages.

14. At all times herein mentioned, the Defendants were engaged in the business of, or were successors in interest to, entities engaged in the business of research, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling,

inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling the prescription drug Axiron for the use and application by Plaintiff.

15. At all times herein mentioned, Defendants were authorized to do business within the state of residence of Plaintiff.

16. At all times herein mentioned, the officers and directors of Defendants participated in, authorized, and directed the production and promotion of the aforementioned product when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of said product and thereby actively participated in the tortious conduct which resulted in the injuries suffered by Plaintiff herein.

17. Plaintiff files this lawsuit within the applicable limitations period of first suspecting that said drugs caused the appreciable harm sustained by Plaintiff. Plaintiff could not, by the exercise of reasonable diligence, have discovered the wrongful case of Plaintiff's injuries at an earlier time because the injuries were caused without perceptible trauma or harm, and when Plaintiff's injuries were discovered their cause was unknown to Plaintiff. Plaintiff did not suspect, nor did Plaintiff have reason to suspect, that Plaintiff had been injured, the cause of the injuries, or the tortious nature of the conduct causing the injuries, until less than the applicable limitations period prior to the filing of this action. Additionally, Plaintiff was prevented from discovering this information sooner because Defendants herein misrepresented and continue to misrepresent to the public and to the medical profession that the drug Axiron is safe and free from serious side effects, and Defendants have fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action.

## OVERVIEW

18. Hypogonadism is a specific condition of the sex glands, which in men may involve the diminished production or nonproduction of testosterone.

19. In 2010, when Defendants announced its FDA approval of Axiron, it asserted that "it has been estimated that up to 13 million men over the age of 45 years in the U.S. may have symptoms associated with low testosterone." Eli Lilly & Co. cited to the prevalence of hypogonadism in males aged at least 45 years.

20. While Defendants were stressing the prevalence of hypogonadism in males, a study published in the Journal of the American Medical Association ("JAMA") in August 2013 entitled "Trends in Androgen Prescribing in the United States, 2001-2011" indicated that many men who get testosterone prescriptions have no evidence of hypogonadism. For example, one third of men prescribed testosterone had a diagnosis of fatigue, and one quarter of men did not even have their testosterone levels tested before they received a testosterone prescription.

21. Defendants coordinated an aggressive advertising campaign designed to convince men that they suffered from low testosterone. Defendants used print and television advertisements, as well as direct mail to promote testosterone. Defendants also, by way of advertisement, offered and promoted a free 30 day trial of Axiron.

22. The advertising campaigns suggest that various symptoms often associated with other conditions may be caused by low testosterone and encourage men to discuss testosterone replacement therapy with their doctors if they experienced any of the "symptoms" of low testosterone. These "symptoms" include listlessness, increased body fat, and moodiness—all general symptoms that are often a result of aging, weight gain, or lifestyle, rather than low testosterone.

23. Since the FDA approved Axiron, Defendants have also sought to convince primary care physicians that low testosterone levels are widely under-diagnosed, and that conditions associated with normal aging could be caused by low testosterone levels.

24. Defendants promoted their product Axiron as easy to use, e.g., "the first testosterone topical solution approved for application via an armpit (underarm) applicator."

25. Defendants convinced millions of men to discuss testosterone replacement therapy with their doctors, and consumers and their physicians relied on Defendants' promises of safety and ease. Although prescription testosterone replacement therapy had been available for years, millions of men who had never been prescribed testosterone flocked to their doctors and pharmacies.

26. What consumers received, however, were not safe drugs, but a product which causes life-threatening problems, including strokes and heart attacks.

27. Defendants successfully promoted and increased sales for Axiron in an already existing market of testosterone replacement therapy drugs. Reports on advertising for testosterone, which included Eli Lilly & Co., stated that spending on print and television advertisements rose by more than 170% in a span of three years – to more than $14 million in 2011, according to advertising tracker Kantar Media. Matthew Perrone, *Testosterone Gets Marketing Push, But Long Term Unknown*, Sept. 10, 2012, *available at*: http://usatoday30.usatoday.com/money/business/story/2012/09/10/testosterone-gets-marketing-push-but-long-term-unknown/57715666/1.

28. Defendants' advertising paid off. By November of 2012, Axiron's market share had grown to 13.3%, and by February of 2013, Axiron comprised 14.6% of the testosterone market. Furthermore, sales of replacement therapies has more than doubled by 2006, and are expected to triple to $5 billion by 2017, according to forecasts by Global Industry Analysts. Shannon Pettypiece, *Are Testosterone Drugs the Next Viagra?*, May 10, 2012, Bloomberg Businessweek, *available at:* http://www.businessweek.com/articles/2012-05-10/are-testosterone-drugs-the-next-viagra.

29. The Defendants' marketing program sought to create the image and belief by consumers and physicians that low testosterone affected a large number of men in the United States and that the use of Axiron is safe for human use, even though Defendants knew these to be false, and even though Defendants had no reasonable grounds to believe them to be true.

30. There have been a number of studies suggesting that testosterone in men increases the risk of heart attacks and strokes.

31. In 2010, a New England Journal of Medicine Study entitled "Adverse Events Associated with Testosterone Administration" was discontinued after an exceedingly high number of men in the testosterone group were suffered adverse events.

32. In November of 2013, a JAMA study was released entitled "Association of Testosterone Therapy with Mortality, Myocardial Infarction, and Stroke in Men with Low Testosterone Levels" which indicated that testosterone therapy raised the risk of death, heart attack and stroke by about 30%.

33. On January 29, 2014, a study was released in PLOS ONE entitled "Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men" which indicated that testosterone use doubled the risk of heart attack with men aged 65 and older, and tripled the risk of a heart attack in younger men with a history of previous heart attacks.

## FACTUAL ALLEGATIONS COMMON TO ALL CAUSES OF ACTION

34. The Food and Drug Administration approved Axiron (2% testosterone solution) on November 23, 2010 for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone: primary hypogonadism; and hypogonatropic hypogonadism. After FDA approval, Axiron was widely advertised and marketed by Defendants as a safe and effective testosterone replacement therapy.

35. Axiron is a topical solution for transdermal use. It contains a strength/dose of 2% testosterone. It is applied to the underarms through an applicator.

36. Testosterone is a primary androgenic hormone responsible for normal growth, development of the male sex organs, and maintenance of secondary sex characteristics.

37. The hormone plays a role in sperm production, fat distribution, maintenance of muscle strength and mass, and sex drive.

38. In men, testosterone levels normally begin a gradual decline after the age of thirty.

39. The average testosterone levels for most men range from 300 to 1,000 nanograms per deciliter of blood. However, testosterone levels can fluctuate greatly depending on many factors, including sleep, time of day, and medication. Resultantly, many men who fall into the hypogonadal range one day will have normal testosterone levels the next.

40. Axiron may produce undesirable side effects to patients who use the drug, including but not limited to, cardiac events, myocardial infarction, stroke, and death.

41. In some patient populations, Axiron use may increase the incidence of myocardial infarctions and death by over 500%.

42. In addition to the above, Axiron has been linked to several severe and life changing medical disorders in both users and those who come into physical contact with users or the unwashed clothes of someone who applied Axiron. Patients taking Axiron may experience enlarged prostates and increased serum prostate-specific antigen levels.

43. Defendants' marketing strategy has been to aggressively market and sell their products by misleading potential users about the prevalence and symptoms of low testosterone and by failing to protect users from serious dangers that Defendants knew or should have known to result from use of its products.

44. Defendants successfully marketed Axiron, increasing its market share to 14.4% by February of 2013. Their campaigns utilized print and television advertising, as well as direct mail, which included promotion of a free 30 day trial.

45. Defendants' advertising program sought to create the image and belief by consumers and their physicians that the use of Axiron was a safe method of alleviating their symptoms, had few side effects and would not interfere with their daily lives, even though Defendants knew or should have known these to be false, and even though the Defendants had no reasonable grounds to believe them to be true.

46. Defendants purposefully downplayed, understated and outright ignored the health hazards and risks associated with using Axiron. Defendants deceived potential Axiron users by relaying positive information through the press, including testimonials from retired professional athletes, and manipulating hypogonadism statistics to suggest widespread disease prevalence, while downplaying known adverse and serious health effects.

47. Defendants concealed material relevant information from potential Axiron users and minimized user and prescriber concern regarding the safety of Axiron.

48. In particular, in the warnings Defendants give in their commercials, online and print advertisements, Defendants fail to mention any potential cardiac or stroke side effects and falsely represents that Defendants adequately tested Axiron for all likely side effects.

49. As a result of Defendants' advertising and marketing, and representations about its product, men in the United States pervasively seek out prescriptions for Axiron. If Plaintiff in this action had known the risks and dangers associated with Axiron, Plaintiff would not have taken Axiron, and consequently would not have been subject to its serious side effects.

## SPECIFIC FACTUAL ALLEGATIONS

50. Plaintiff was prescribed Axiron and used it as directed from approximately April, 2011 until August, 2012.

51. Plaintiff was seventy (70) years of age when he was prescribed and used testosterone for symptoms he attributed to low testosterone after viewing Defendant's advertisements.

52. Plaintiff was very healthy and had no history of heart disease prior to taking testosterone. In keeping with his healthy and proactive lifestyle, Plaintiff agreed to initiate testosterone treatment.

53. Plaintiff was diagnosed with a pulmonary embolism ("PE") and deep vein thrombosis ("DVT") on or about October 11, 2012. As a result, he was hospitalized, and for the rest of his life, he must take medication. Due to his severe clotting events, he is now at markedly increased risk of additional cardiovascular disease, cerebrovascular accidents, and death.

54. Had Defendants properly disclosed the risks associated with testosterone, Plaintiff would have avoided the risk of PE and DVT by either not using testosterone at all, severely limiting the dosage and length of use, and/or by closely monitoring the degree to which the drugs were adversely affecting his health.

55. Plaintiff files this lawsuit within two (2) years of first suspecting that the Axiron was the cause of appreciable harm sustained by Plaintiff, within two (2) years of first suspecting or having reason to suspect any wrongdoing, and within the applicable limitations period of first discovering their injuries and the wrongful conduct that cause such injuries. Plaintiff could not by the exercise of reasonable diligence have discovered any wrongdoing, nor could Plaintiff have discovered the causes of his injuries at an earlier time because some injuries occurred without

initial perceptible trauma or harm, and when Plaintiff's injuries were discovered, their causes were not immediately known.

56. Plaintiff did not suspect, nor did he have reason to suspect, that wrongdoing had caused his injuries, nor did Plaintiff have reason to suspect the tortious nature of the conduct causing the injuries, until recently and has filed the herein action well within the applicable statute of limitations period. Plaintiff had no knowledge of the defects in the Axiron and the wrongful conduct of the Defendant as set forth herein, nor did Plaintiff have access to the information regarding other injuries and complaints in the possession of Defendant. Additionally, Plaintiff was prevented from discovering this information sooner because Defendant herein misrepresented and continue to misrepresent to the public, to the medical profession and to Plaintiff that the Axiron is safe and free from serious defects and side effects and Defendant has fraudulently concealed facts and information that could have led Plaintiff to an earlier discovery of potential causes of action.

57. As alleged herein, as a direct, proximate, and legal result of Defendants' negligence and wrongful conduct, and the unreasonably dangerous and defective characteristics of the drug testosterone, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to heart attack. Plaintiff has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment and will continue to incur such expenses in the future. Plaintiff seeks actual damages from Defendant as alleged herein.

## FIRST CAUSE OF ACTION
## STRICT LIABILITY – FAILURE TO WARN

58. Plaintiff incorporates by reference herein each of the allegations heretofore set forth in this Complaint as though fully set forth herein.

59. The Axiron manufactured and/or supplied by Defendants was defective due to inadequate warnings or instructions because Defendants knew or should have known that the product created significant risks of serious bodily harm to consumers, and they failed to adequately warn consumers and/or their health care providers of such risks. The Axiron manufactured and/or supplied by Defendants was defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of serious bodily harm from the use of Axiron, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury.

60. As a direct and proximate result of Plaintiff's reasonably anticipated use of Axiron as manufactured, designed, sold, supplied, marketed and/or introduced into the stream of commerce by Defendants, Plaintiff suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages and losses in the future.

**SECOND CAUSE OF ACTION**
**NEGLIGENCE**

61. Plaintiff incorporates by reference herein each of the allegations set forth in this Complaint as though set forth herein.

62. At all times herein mentioned, Defendants had a duty to properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect, research, distribute, market, label, package, distribute, prepare for use, sell, prescribe and adequately warn of the risks and dangers of Axiron.

63. At all times herein mentioned, Defendants negligently and carelessly manufactured, designed, formulated, distributed, compounded, produced, processed, assembled,

inspected, distributed, marketed, labeled, packaged, prepared for use and sold Axiron and failed to adequately test and warn of the risks and dangers of Axiron.

64. Despite the fact that Defendants knew or should have known that Axiron caused unreasonable, dangerous side effects, Defendants continued to market Axiron to consumers including Plaintiff, when there were safer alternative methods of treating loss of energy, libido erectile dysfunction, depression, loss of muscle mass and other conditions Axiron's advertising claims are caused by low testosterone.

65. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

66. Defendants' negligence was a proximate cause of Plaintiff's injuries, harm and economic loss which Plaintiff suffered, and will continue to suffer, as described and prayed for herein.

**THIRD CAUSE OF ACTION**
**FOR BREACH OF IMPLIED WARRANTY**

67. Plaintiff incorporates by reference here each of the allegations heretofore set forth in this Complaint as though fully set forth herein.

68. Prior to the time that the aforementioned products were used by Plaintiff, Defendants impliedly warranted to Plaintiff and Plaintiff's agents and physicians that Axiron was of merchantable quality and safe and fit for the use for which it was intended.

69. Plaintiff was and is unskilled in the research, design and manufacture of the products and reasonably relied entirely on the skill, judgment and implied warranty of the Defendants in using Axiron.

70. Axiron was neither safe for its intended use nor of merchantable quality, as warranted by Defendants, in that Axiron has dangerous propensities when used as intended and will cause severe injuries to users.

71. As a result of the abovementioned breach of implied warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

**FOURTH CAUSE OF ACTION**
**FOR BREACH OF EXPRESS WARRANTY**

72. Plaintiff incorporates by reference here each of the allegations set forth in this Complaint as though fully set forth here.

73. At all times mentioned, Defendants expressly represented and warranted to Plaintiff and Plaintiff's agents and physicians, by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that Axiron is safe, effective, fit and proper for its intended use. Plaintiff purchased Axiron relying upon these warranties.

74. In utilizing Axiron, Plaintiff relied on the skill, judgment, representations, and foregoing express warranties of Defendants. These warranties and representations were false in that Axiron is unsafe and unfit for its intended uses.

75. As a result of the abovementioned breach of express warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

**FIFTH CAUSE OF ACTION**
**FRAUD**

76. Plaintiff incorporates by reference here each of the allegations set forth in this Complaint as though set forth fully herein.

77. Defendants, from the time they first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed Axiron, and up to the present, willfully deceived Plaintiff by concealing from them, Plaintiff's physicians and the general public, the true facts concerning Axiron, which the Defendants had a duty to disclose.

78. At all times herein mentioned, Defendants conducted a sales and marketing campaign to promote the sale of Axiron and willfully deceive Plaintiff, Plaintiff's physicians and the general public as to the benefits, health risks and consequences of using Axiron. Defendants knew of the foregoing, that Axiron is not safe, fit and effective for human consumption, that using Axiron is hazardous to health, and that Axiron has a serious propensity to cause serious injuries to its users, including but not limited to the injuries Plaintiff suffered.

79. Defendants concealed and suppressed the true facts concerning Axiron with the intent to defraud Plaintiff, in that Defendants knew that Plaintiff physicians would not prescribe Axiron, and Plaintiff would not have used Axiron, if they were aware of the true facts concerning its dangers.

80. As a result of Defendants' fraudulent and deceitful conduct, Plaintiff suffered injuries and damages as alleged herein.

**SIXTH CAUSE OF ACTION**
**NEGLIGENT MISREPRESENTATION**

81. Plaintiff incorporates by reference herein each of the allegations set forth in this Complaint as though fully set forth herein.

82. From the time Axiron was first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, Defendants made misrepresentations to Plaintiff, Plaintiff's physicians and the general public, including but not limited to the misrepresentation that Axiron was safe, fit and effective for human consumption.

At all times mentioned, Defendants conducted a sales and marketing campaign to promote the sale of Axiron and willfully deceive Plaintiff, Plaintiff's physicians and the general public as to the health risks and consequences of the use of the abovementioned product.

83. The Defendants made the foregoing representation without any reasonable ground for believing them to be true. These representations were made directly by Defendants, by sales representatives and other authorized agents of Defendants, and in publications and other written materials directed to physicians, medical patients and the public, with the intention of inducing reliance and the prescription, purchase and use of the subject product.

84. The representations by the Defendants were in fact false, in that Axiron is not safe, fit and effective for human consumption, using Axiron is hazardous to health, and Axiron has a serious propensity to cause serious injuries to users, including but not limited to the injuries suffered by Plaintiff.

85. The foregoing representations by Defendants, and each of them, were made with the intention of inducing reliance and the prescription, purchase and use of Axiron.

86. In reliance of the misrepresentations by the Defendants, and each of them, Plaintiff was induced to purchase and use Axiron. If Plaintiff had known of the true facts and the facts concealed by the Defendants, Plaintiff would not have used Axiron. The reliance of Plaintiff upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts.

87. As a result of the foregoing negligent misrepresentations by Defendants, Plaintiff suffered injuries and damages as alleged herein.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment against Defendants as follows:

(a) For general damages in a sum in excess of the jurisdictional minimum of this Court;

(b) For medical, incidental, and hospital expenses according to proof;

(c) For pre-judgment and post-judgment interest as provided by law;

(d) For full refund of all purchase costs Plaintiff paid for testosterone;

(e) For compensatory damages in excess of the jurisdictional minimum of this Court;

(f) For consequential damages in excess of the jurisdictional minimum of this Court;

(g) For attorneys' fees, expenses, and costs of this action; and

(h) For such further relief as this Court deems necessary, just, and proper.

## DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and as to all issues.

Dated: October 6, 2014

Respectfully submitted,

*/s/ Timothy J. Becker*

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